

### **REMARKS/ARGUMENTS**

Claims 1, 36, 38–60 and 64 are pending in the instant application.

The Examiner has rejected claims 1, 36, 37, 40, 45, 47, 49 and 57 under 35 U.S.C. § 102(b) as being “anticipated by Cottingham et al. (WO 97/10056, 03/20/1997)”.

Specifically, the Examiner states, “Cottingham et al. teach an apparatus for performing biological reactions (see whole doc. esp. abstract & figure 4, DNA amplification and probe assay device) comprising a substrate (see page 13 line 3-4 DNA card with bottom and top layer) and an array with biomolecular probes positioned on first surface (see page 10 lines 1-15 teaching an array arrangement of DNA amplification and assay reagents which includes primers and probes spotted on surface) and flexible layer affixed to first surface by an adhesive layer forming reaction volume (see page 13 lines 9 & 10 adhesive binding a plastic film) and port (see page 13 line 21 & last line air vent and sample port). The ports extend through flexible layer (see Figure 4 detail 28 & 26).”

The Examiner continues, “The apparatus taught by Cottingham et al. is apparently watertight, as a port is described for entry of the sample. Cottingham et al. also do not describe sample leakage indicating the sample chamber is watertight (see p. 5 second

paragraph). They teach apparatus may further comprise measuring instrument and heated carrier (see figure 13 detail 80, 81 and page 21 first full paragraph)".

In response, Applicant respectfully asserts that the Examiner has mischaracterized. Specifically, as stated in the cited portion of the Cottingham, et al. reference, "The DNA card 20 (the apparatus of Cottingham et al) is made up of a bottom layer 40, a middle layer 42 and a top layer 44. The seals 36 of the sealing strip 32 are adhered to the upper surface 46 of the top layer 44. Each of the layers 40, 42 and 44 is preferably made of a plastic film having a thickness of approximately 0.015 inches, and the seals 36 are of a similar material and thickness. The layers 40, 42 and 44 (together with the seals 36) are held together by a pressure sensitive adhesive (not shown) that is typically about 0.001 inch thick" (see page 13, lines 3–10).

Thus, quite different from the instant invention where the substrate has an upper and a lower surface, the Cards of Cottingham, et al. are comprised of three separate plastic layers which are held together by pressure sensitive adhesives between each layer. Such is neither disclosed nor even suggested in the instant invention.

Further, Cottingham, et al. does not teach or disclose an array of biomolecular probes positioned in the first surface of the substrate within a reaction volume (or sample

chamber), but rather teaches a plurality of sample chambers contained on the Card, each sample chamber containing a single spot of reagent (see e.g., page 13, line 16).

Additionally, contrary to the Examiner's assertion, Cottingham, et al. neither discloses nor even suggests that the chambers are watertight, inasmuch as it does not mention this property at all. Applicant respectfully asserts that for the Examiner to properly maintain an objection under 35 U.S.C. § 102(b), the features must be positively recited, and not merely inferred from the fact that the Cottingham, et al. reference does not describe sample leakage.

In view of the foregoing, Applicant respectfully asserts the Examiner's rejections cannot be sustained and should be withdrawn.

The Examiner has rejected claim 43 and 44 under 35 U.S.C. § 103(a) as "being unpatentable over Cottingham et al. (WO 97/10056, 03/20/1997) in view of Rehman et al. (Nucleic Acids Research, January 1999)".

Specifically, the Examiner states, "The teachings of Cottingham et al. are described previously. Cottingham et al. do not teach polyacrylamide. Rehman et al. teach polyacrylamide layer for binding probes (see p. 649, Introduction paragraph 2). One of ordinary skill in the art would have been motivated to apply polyacrylamide as

taught by Rehman et al. (Nucleic Acids Research, January 1999) polyacrylamide to the device as taught by Cottingham et al. (WO 97/10056, 03/20/1997) in order to immobilize DNA probes at a greater capacity”.

The Examiner continues, “Rehman et al. (Nucleic Acids Research, January 1999) state that polyacrylamide provides for great probe capacity, density, lower non-specific binding levels and relatively high thermal stability particularly in amplifications of solid phase PCR and hybridization assays (see p. 649, paragraph 2). It would have been prima facie obvious to apply the polyacrylamide as taught by Rehman et al. (Nucleic Acids Research, January 1999) to the device as taught by Cottingham et al. (WO 97/10056, 03/20/1997) for DNA probe assays in order to increase the hybridization efficiency of the probe reagents”.

In response, Applicant reiterates the arguments as to the inapplicability of the Cottingham, et al. reference, and respectfully submits that the addition of the Rehman, et al. does nothing to remedy these deficiencies.

In view of the foregoing, Applicant respectfully asserts the Examiner’s rejections cannot be sustained and should be withdrawn.

The Examiner has rejected claims 48, 50–56 and 60 under 35 U.S.C. § 103(a) as “being unpatentable over Cottingham et al. (WO 97/10056, 03/20/1997) in view of Bjornson et al. (WO 99/19717, 04/22/1999)”.

Specifically, the Examiner states, “The teachings of Cottingham et al. are described previously. Cottingham do not teach flexible layer with polyester, polypropylene. Bjornson et al, teach a variety of well known flexible films such ms plastics acrylics and polyethylenes of varying widths (see p. 17 line 15-17). Bjornson et al. teach rolling with roller (see figure 5). Bjornson et al. teach adhesives (see page 25 line 9)”.

The Examiner further states, “One of ordinary skill in the art would have been motivated to apply rollers and flexible films as taught by Bjornson et al. (WO 99/19717, 04/22/1999) to the device as taught by Cottingham et al. (WO 97/10056, 03/20/1997) in order to construct a cover for the reaction and press to ensure a seal of the film. It would have been prima facie obvious to apply rollers and flexible films as taught by Bjornson et al. (WO 99/19717, 04/22/1999) to the device as taught by Cottingham et al. (WO 97/10056, 03/20/1997) in order to ensure a sealed layer in Cottingham’s device”.

In response, Applicant reasserts the discussion above as to the deficiencies of Cottingham, et al and respectfully submits that the addition of Bjornson, et al. reference does nothing to remedy these deficiencies.

In view of the foregoing, Applicant respectfully asserts the Examiner's rejections cannot be sustained and should be withdrawn.

The Examiner has rejected claims 39, 41, 42, 46, 58 and 59 under 35 U.S.C. § 103(a) as "being unpatentable over Cottingham et al. (WO 97/10056, 03/20/1997) in view Besemer et al. (USPN 5,945,334, 08/31/1999)".

Specifically, the Examiner states, "The teachings of Cottingham et al. are described previously. Cottingham et al. do not teach sample chip and heater Besemer et al. teach a chip device containing a substrate having an array of probes attached to cavity (see col. 1 line 65- col. 2 line 3 & claims 1 & 2). The body includes two inlets that allow fluids into and through cavity. A seal, plug or any other seal may be provided for each inlet to retain fluid within cavity (see col. 6 line 39). The body is formed by welding two pieces together. Besemer et al. also teach heaters may be connected to device (col. 9 line 62). Besemer et al. also teach of variety of surface supports including glass, silicon, Ge, GaAS (see col. 4 line 60-64)".

The Examiner continues, "One of ordinary skill in the art would have been motivated to use chips as taught by Besemer et al. (USPN 5,945,334, 08/31/1999) with the device as taught by Cottingham et al. (WO 97/10056, 03/20/1997) in order perform hybridization assays. Array chips were well known and commonly practiced in the art to perform detection assays. It would have been prima facie obvious to use chips as taught by Besemer et al. (USPN 5,945,334, 08/31/1999) with the device as taught by Cottingham et al. (WO 97/10056, 03/20/1997) in order to perform a plurality of different assays simultaneously".

In response, Applicant reiterates the arguments as to the inapplicability of the teachings of Cottingham, et al and respectfully asserts that the addition of Besemer, et al. does not remedy these deficiencies.

In view of the foregoing, Applicant respectfully asserts the Examiner's rejections cannot be sustained and should be withdrawn.

The Examiner has rejected claim 64 under 35 U.S.C. § 103(a) as "being unpatentable over Cottingham et al. (WO 97/10056, 03/20/1997) in view of Besemer et al. (USPN 5,945,334, 08/31/1999) in further view of Van Antwerp et al. (USPN 5,786,439, 07/28/1998)".

Specifically, the Examiner states, “The teachings of Cottingham et al. and Besemer et al. are described previously. Cottingham et al. do not teach the claimed layer of water-soluble compound. Van Antwerp et al. teach coating the surface of biosensor with uniform hydrogel (see abstract). The hydrogel may be PEG 600 (see claim 10)”.

The Examiner further states, “One of ordinary skill in the art would have been motivated to apply PEG-600 coatings as taught by Van Antwerp et al. (USPN 5,786,439, 07/28/1998) to the chip array device as taught by Cottingham et al. (WO 97/10056, 03/20/1997) and Besemer et al. in order to protect the array from interfering chemicals. Antwerp et al state that the hydrogel layer protects from interfering chemicals such as electrolytes and proteins but allows water to pass through to allow the arrays to accurately measure analyte (see column 1 lines 46-50). It would have been prima facie obvious to apply hydrogel as taught by Van Antwerp et al. (USPN 5,786,439, 07/28/1998) to the chip array device as taught by Cottingham et al. (WO 97/10056, 03/20/1997) and Besemer et al. in order to allow the array to accurately measure analytes without interference from other chemicals”.

In response, Applicant reiterates the arguments above as to the inapplicability of Cottingham, et al. and Besemer, et al. and respectfully asserts that the addition of the Van Antwerp, et al. reference does nothing to remedy the deficiencies.




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In view of the foregoing, Applicant respectfully asserts the Examiner's rejections cannot be sustained and should be withdrawn.

In view of the foregoing, Applicant respectfully asserts the Examiner's rejections cannot be sustained and should be withdrawn. Applicant believes that the claims are in allowable form and earnestly solicit the allowance of claims 1, 36, 38-60 and 64.

Respectfully submitted,

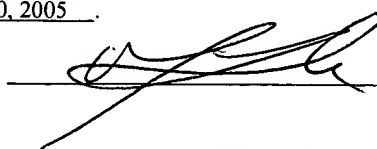
AMERSHAM BIOSCIENCES CORP

By:   
Royal N. Ronning, Jr.  
Reg. No.: 32,529  
Attorney for Applicant

Amersham Biosciences Corp  
800 Centennial Avenue  
P. O. Box 1327  
Piscataway, New Jersey 08855-1327

Tel: (732) 457-8423  
Fax: (732) 457-8463

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Signature: 

Name: Melissa Leck